

Attorney Docket No.: F.003

24 (twice amended). The method of claim 23 wherein said applying step comprises placing the drape on the body such that the body is disposed between at least two opposing portions of the indicia region of the drape, said placing of the drape further providing that each said portion of the indicia region of the drape is contained in a  
5 separate plane which is in parallel separation to the other plane.

### REMARKS

Applicant submitted a "Proposed Amendment" dated September 30, 2002 for the above-identified application. Applicant understands from a telephone conference between the undersigned and Supervisory Patent Examiner M. Lateef that this "Proposed Amendment" has not been formally entered into the record of the above-identified application by the U.S. Patent and Trademark Office (PTO). Applicant requests that the "Proposed Amendment" remain un-entered in the record of the above-identified application.

Applicant appreciates the interviews granted by Examiner Mercader on October 2, 2002 and by Supervisory Patent Examiner Lateef on October 10, and November 7, 2002.

Entry of the present "Response to Final Action" in the record of the above-identified application by the PTO is requested. Attached hereto are substitute pages entitled "Claims 23 and 24 - Version with markings to show changes made". 37 C.F.R. § 1.121, MPEP § 714 (August 2001).

Reconsideration of the above-identified application comprising claims 11, 12, 15, 16 to 21, 23, 24, 25, 28 and 29 in view of the foregoing amendments and following remarks is hereby requested.

Attorney Docket No.: F.003

Claims 11, 12, 15

Claim 11 has not been amended by the present "Response to Final Action". Accordingly, claim 11 is presently the same as claim 11 prior to the Final Action.

Claim 11 contains several specific limitations each of which is significant. One of these limitations is that the antimicrobial drape has a cylindrical portion which is closed at one end by a hemispherical portion. Embodiments of such a drape are disclosed in the specification of the above-identified application, as originally filed, on p. 25, line 8 to p. 26, line 27. Also, the embodiments are shown in Figs. 26 to 30 of the specification. Another significant limitation of claim 11 is that the drape is "formed of expandable material and sized to have an internal volume which is less than the volume of the elongate body enabling said drape to be shrink-fitted onto the body" (emphasis added).

U.S. Patent No. 5,260,985 (Mosby) does not disclose or suggest an antimicrobial drape having the shape specified by claim 11 (i.e., the cylindrical and hemispherical portions) and the internal volume which is sized (relative to the elongate body) to enable the shrink-fitting as defined by claim 11. In contrast, Mosby discloses a "flat transparent sheet" (e.g., col. 4, line 44, emphasis added) which may be applied to a human breast to conform to the breast. Thus, the flat sheet of Mosby takes the shape of a human breast only as a result of application thereto. There is no disclosure or suggestion in Mosby for the flat sheet of Mosby to have an internal volume, which is less than the volume of the breast disclosed therein, prior to application of the drape to the breast. A prior internal volume of the drape is explicitly required by claim 11 for enabling the "shrink-fitting". Accordingly, Mosby in no way shows or suggests the drape having the shape and size defined by claim 11.

Attorney Docket No.: F.003

Additionally, the cylindrical and hemispherical portions defined by claim 11 are not shown or suggested by the sheet of Mosby. The sheet of Mosby, when applied to the human breast shown therein (Figs. 3, 4, 6 to 8), has the shape of a paraboloid or cone, and not a cylinder closed at one end by a hemisphere. In contrast, the cylindrical and hemispherical portions of the drape defined by claim 11 facilitate application of the drape to a human finger, as shown in Figs. 27 and 30 of the specification of the above-identified application. Thus, the specific shape of the drape defined by claim 11 (i.e., having cylindrical and hemispherical portions) provides significant advantages which are in no way shown or suggested by Mosby.

U.S. Patent No. 4,899,762 (Muller) like Mosby, discloses a flat drape (e.g., Figs. 1 to 11) which conforms to the surface of the patient's body. Also, like Mosby, Muller does not disclose or suggest the limitation of claim 11 that the drape is "formed of expandable material and sized to have an internal volume which is less than the volume of the elongate body enabling said drape to be shrink-fitted onto the body" (emphasis added). Additionally, like Mosby, Muller does not disclose or suggest a drape having a cylindrical portion which is closed at one end by a hemispherical portion. Accordingly, for the same reasons stated in the foregoing for Mosby, claim 11 is not shown or suggested by Muller.

Regarding claim 11, the Final Action, at p. 3, states "[t]he definition of 'conforming' inherently includes 'shaping' or an alternative phraseology as disclosed by the current application as 'shrink-fitted.'" The Final Action fails to explain how "'conforming' inherently includes ... 'shrink-fitted'" (emphasis added). This conclusory statement cannot provide a basis for the rejection of claim 11, in view of the complete absence of any specific support for the statement in the Final Action (e.g., reference to specific portions of the prior art). Additionally, as explained in the

Attorney Docket No.: F.003

foregoing, "shrink-fitting" as defined by claim 11 is in no way disclosed or suggested by "conforming".

Moreover, the Final Action fails to explain how claim 11, in its entirety, is shown or suggested by the prior art. Each and every limitation of claim 11 is significant. The Final Action fails to acknowledge each limitation of claim 11, and fails to provide a specific showing of how the claim (*i.e.*, limitation by limitation) is not patentable in view of the prior art (*e.g.*, reference to specific portions of the prior art and consideration of claim 11 in its entirety). This is illustrated by ¶ 2, p. 4 to 5 of the Final Action.

Accordingly, the rejection of claim 11 should be withdrawn, and such action is requested.

Claims 12 and 15 have not been amended by the present "Response to Final Action". Accordingly, these claims are presently the same as prior to the Final Action. Claims 12 and 15 depend directly from claim 11. Accordingly, the rejection of these dependent claims should be withdrawn for the same reasons as for claim 11, and such action is requested.

#### Claims 16 to 21

Claim 16 has not been amended by the present "Response to Final Action". Accordingly, claim 16 is presently the same as claim 16 prior to the Final Action.

Claim 16 contains several specific limitations each of which is significant. One of these limitations is "a conical antimicrobial drape having sufficient flexibility to conform to at least a portion of an outer surface of the conical body". Another of these limitations is that the drape has "a longitudinally extending radial cutout comprising a base which

Attorney Docket No.: F.003

coincides with a peripheral edge of" the drape. An embodiment of such a drape is disclosed in the specification of the above-identified application, as originally filed, on p. 26, line 29 to p. 28, line 31. Also, the embodiment is shown in Figs. 31 to 36 of the specification. The "longitudinally extending radial cutout" is designated by reference numeral 206 (p. 27, lines 6 to 7), the "base" is designated by reference numeral 209 (p. 27, line 7), and the "peripheral edge" of the drape is designated by reference numeral 204 (p. 27, line 8). The physical relationship of these parts, as defined by claim 16, is shown in Figs. 31 and 32 and described on p. 27, lines 6 to 9. The "longitudinally extending radial cutout" defined by claim 16 is significant because it provides circumferential flexibility to the drape thereby increasing the range of sizes of breasts to which the drape may be closely applied.

Mosby does not disclose or suggest a "conical" drape having a "longitudinally extending radial cutout" as specified by claim 16. As discussed in the foregoing, Mosby discloses a "flat transparent sheet" (e.g., col. 4, line 44, emphasis added) which may be applied to a human breast to conform to the breast. The "sheet" of Mosby appears to be continuous as shown, for example, in Figs. 1 and 2 thereof. No mention is made anywhere in Mosby of any portion of the sheet which would disclose or suggest the "longitudinally extending radial cutout" specified by claim 16.

The Final Action, at p. 3, states that Mosby "describes a 'cut-out' for the nipple". Assuming *arguendo* that Mosby contains such a description, this, in no way, discloses or suggests the a "longitudinally extending radial cutout" specified by claim 16 because the "cut-out" for the nipple" arguably disclosed by Mosby is not "longitudinal" and lacks a "base which coincides with a peripheral edge" of the drape, as defined by claim 16. The terms "longitudinal cutout" and "base of the cutout", and the phrase "base which coincides with a peripheral edge" of the drape each have clear meanings in view of claim 16 in its entirety. This is confirmed by the specification of the above-identified

Attorney Docket No.: F.003

application. Accordingly, the "longitudinal cutout ... comprising a base which coincides with a peripheral edge of [the] drape" is not shown or suggested by a "'cut-out' for the nipple" arguably disclosed by Mosby.

Muller fails to show or suggest a conical drape having a "longitudinally extending radial cutout" as defined by claim 16.

Accordingly, the rejection of claim 16 should be withdrawn, and such action is requested.

Claims 17 to 21 have not been amended by the present "Response to Final Action". Accordingly, these claims are presently the same as prior to the Final Action. Claims 17 to 21 depend directly or indirectly from claim 16. Accordingly, the rejection of these dependent claims should be withdrawn for the same reasons as for claim 16, and such action is requested.

#### Claims 23 to 25

Claim 23, as amended herein, is claim 23 prior to the Final Action rewritten to include the entirety of claim 22 prior to the Final Action. No other changes have been made to claim 23, as amended herein.

Claim 23 defines a method containing several specific steps each of which is significant. One of these steps is "a first directing of imaging radiation through [the] drape and indicia such that a first radiographic image of [the] body and indicia is formed on a medium, the portion of the drape having the indicia which cause the formation of the indicia image defining an indicia region of the drape". Thus, the "indicia region" is the portion of the drape having the indicia which creates the "indicia image". For example,

Attorney Docket No.: F.003

this will be the central portion of the drape. Also, there may be some indicia outside of the indicia region, e.g., if such indicia do not appear as an "indicia image" on the radiographic "medium".

Further steps defined by claim 23 include "a first referencing on the radiographic image of the selected portion within the body" and "a first locating of the selected portion within the body by referencing the body relative to the indicia on the drape in a manner corresponding to said first referencing of the radiographic image". This enables locating a specific "selected portion" of the body by reference to the indicia image on the radiographic "medium".

Claim 23 defines further steps of "providing sufficiently unobstructed access to the indicia region ..." and "making a surgical incision through the indicia region of the drape and into the body sufficient to access the selected portion, the step of making a surgical incision through the indicia region of the drape comprising placing of the hand of the operator in direct contact with the indicia region". Thus, sufficient access is provided to the indicia region to enable the hand of the operator to be placed "in direct contact with the indicia region".

Claim 23 defines further second directing, referencing and locating steps which correspond to the first directing, referencing and locating steps described in the foregoing. Claim 23 thereby defines a method in which the directing, referencing and locating steps occur both before and after the operator has made a surgical incision which includes the operator's hand directly contacting the indicia region.

This sequence of the directing, referencing and locating steps allows the operator to target a specific "selected portion" of the body, and then make a surgical incision by placing the operator's hand in direct contact with the indicia region. Such direct contact

Attorney Docket No.: F.003

facilitates the making of the incision because the hand of the operator may be stabilized on the indicia region (which is fixed to the body, as defined by claim 23) thereby facilitating control of the making of the incision (e.g., increased precision in the location and size of the incision). The repeating of the directing, referencing and locating steps after the making of the incision provides significant advantages because it facilitates determination of whether the "selected portion" is actually located in the actual body.

The method of claim 23 is in no way disclosed or suggested by Mosby. Assuming *arguendo* that the "sheet" of Mosby includes a portion corresponding to the "indicia region" defined by claim 23, such a portion of Mosby is obstructed from being contacted directly by the operator's hand according to claim 23. This obstruction results from the "indicia region" of Mosby being enclosed by the "box-like apparatus". Mosby does not disclose "localization" without the "box-like apparatus". Instead, Mosby discloses the "box-like apparatus" to be important for preventing movement of the "human body part" during localization (col. 2, line 10 to col. 3, line 15). In fact, Mosby indicates that, if the "box-like apparatus" is removed, then the "sheet" is also removed (col. 3, lines 9 to 15, "composite" defined as including the "box-like apparatus", i.e., "control apparatus", and the "sheet", i.e., "conforming biopsy grid"). Thus, Mosby discloses the use of the "sheet" with the "box-like apparatus" which prevents the hand of the operator from being placed "in direct contact with" the portion of the "sheet" of Mosby which may arguably correspond to the "indicia region" of claim 23. Therefore, Mosby does not disclose or suggest the directing, referencing and locating steps both before and after the making of the incision, and the making of the incision including the placing of the operator's hand "in direct contact with the indicia region" as defined by claim 23. Only with the hindsight benefit of the above-identified application (which is impermissible) could the contrary be found. Accordingly, the method defined by claim 23 is not disclosed or suggested by Mosby.



Attorney Docket No.: F.003

The Final Action, at p. 3, states "the reference to the 'box-like' apparatus is inapplicable because the current invention by its claimed language does not exclude such use." Admittedly, claim 23 contains no exclusionary limitation. Nevertheless, claim 23 defines a method which is not shown or suggested by Mosby. This is plainly evident if the entire series of steps defined by claim 23 is considered in view of Mosby. Thus, the lack of any exclusionary limitation in claim 23 provides no support for the rejection of claim 23 in view of Mosby.

Muller fails to show or suggest a method as defined by claim 23 including the directing, referencing and locating steps both before and after the making of the incision, and the making of the incision including the placing of the operator's hand "in direct contact with the indicia region".

The Final Action fails to explicitly acknowledge the limitation added by claim 23 (when claim 23 was dependent from claim 22, prior to the Final Action), e.g., "placing of the hand of the operator in direct contact with the indicia region." This is illustrated by the portion of p. 3 of the Final Action following "Regarding Claims 22-27". Each and every limitation of claim 23 is significant.

Moreover, the Final Action fails to explain how claim 23, in its entirety, is shown or suggested by the prior art. The Final Action fails to provide a specific showing of how the claim (*i.e.*, limitation by limitation) is not patentable in view of the prior art (*e.g.*, reference to specific portions of the prior art and consideration of claim 23 in its entirety). This is illustrated by ¶ 2, p. 4 to 5 of the Final Action.

Claim 24 has been amended solely to depend from claim 23 rather than claim 22 which has been cancelled in the present "Response to Final Action". Claim 25 has not been amended by the present "Response to Final Action". Accordingly, except for the

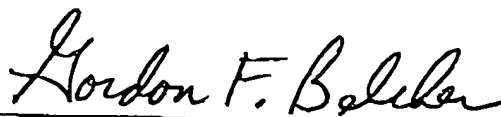
Attorney Docket No.: F.003

amendment to claim 24, claims 24 and 25 are presently the same as the respective claims prior to the Final Action. Claims 24 and 25 depend directly or indirectly from claim 23. Accordingly, the rejection of these dependent claims should be withdrawn for the same reasons as for claim 23, and such action is requested.

The foregoing is submitted as being fully responsive to the Final Action including the rejections contained therein. Accordingly, the above-identified application is submitted as being allowable and allowance thereof is requested.

If the Examiner has any questions about the above, Applicant's Attorney Gordon F. Belcher is requested to be contacted at the below-identified telephone number. Additionally, please address all future correspondence to the below-identified address.

Respectfully submitted,



Gordon F. Belcher  
Registration No. 33,156  
Attorney for Applicant  
MORGAN, LEWIS & BOCKIUS, I.L.P.  
101 Park Avenue  
New York, New York 10178  
Telephone No. (212) 309-2125

Attorney Docket No.: F.003

**Claims 23 and 24 – Version with markings to show changes made**

Deletions are contained in "[ ]", and insertions are underlined.

23 (twice amended). [The method of claim 22 wherein] A method for correlating a selected portion within a body to a radiographic image of the body for treatment of the body, said method comprising the steps of:

applying a radio-transparent drape having radio-opaque indicia to the body;

fixing said drape and indicia to the body;

a first directing of imaging radiation through said drape and indicia such that a first radiographic image of said body and indicia is formed on a medium, the portion of the drape having the indicia which cause the formation of the indicia image defining an indicia region of the drape;

a first referencing on the radiographic image of the selected portion within the body relative to the indicia;

a first locating of the selected portion within the body by referencing the body relative to the indicia on the drape in a manner corresponding to said first referencing of the radiographic image;

providing sufficiently unobstructed access to the indicia region of the drape to enable positioning by the hand of the operator adjacent to the indicia region of the drape;

making a surgical incision through the indicia region of the drape and into the body sufficient to access the selected portion, the step of making a surgical incision through the indicia region of the drape [comprises] comprising placing of the hand of the operator in direct contact with the indicia region;

a second directing of imaging radiation through said drape and indicia such that a radiographic image of said body and indicia is formed on the medium;

a second referencing on the radiographic image of the selected portion within the body relative to the indicia; and

a second locating of the selected portion within the body by referencing the body relative to the indicia on the drape in a manner corresponding to said second referencing of the radiographic image.

24 (twice amended). The method of claim [22] 23 wherein said applying step comprises placing the drape on the body such that the body is disposed between at least two opposing portions of the indicia region of the drape, said placing of the drape further providing that each said portion of the indicia region of the drape is contained in a separate plane which is in parallel separation to the other plane.